Nutrition/Interventional - HUNGARY

Competent authority

Contact Details

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Additional Information

Co-authority: ETT KFEB (Hungarian Medical Research Council Ethics Committee for Clinical Pharmacology)
Co-authority for non-interventional trials: ETT TUKEB
Co-authority for trials conntected with reproduction: ETT HRB (Committee of Human Reproduction)

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Institutional Competent Authority
National Competent Authorities
Regional Ethics Committee

Regulatory and ethics bodies involved in approval process for trials including patients

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Regulatory and ethics bodies involved in approval process for trials including including healthy participants

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Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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CA - Registration/ notification without approval required for

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	CA - Registration requirements for clinical trials Registration mandatory **Registration requirements for clinical trials including patients** – **Registration requirements for clinical trials including healthy participants** – **Registration requirements for clinical trials including vulnerable population** – **CA - Submission required to** Institutional CA **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Submission Format	**Standard application form available** Yes
Language of Submission	**Language(s) of application** Official national language Hungarian **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** No **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** –
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 2

	Time to approval of CA in weeks (maximum) 20 **Time to approval CA in weeks (average)** 12
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Central Ethics Committee (CEC)/ Public co-authority for IMP studies: **Contact Name 2** Committee for Clinical Pharmacology and Ethics of the Medical Research Council – KFEB **Phone** (+36 1) 795-1195 or (+36 1) 795-4873 **Fax** (+36 1) 795-0168 **Country** Hungary (HU) **E-Mail** kfebtitkarsag@emmi.gov.hu **Web address** http://www.ett.hu/kfeb.htm
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** –
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Institutional EC **Ethical approval (favourable opinion) for trials including patients to be obtained from** – **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** –

Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** –
Submission of Application	**Entitled to study submission** Principal Investigator Investigator Physician **Entitled to submission of trials including patients** – **Entitled to submission of trials including healthy participants** – **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** Proof of GCP Training of applicant Application is limited to the institution
Language of Submission	**Language(s) of application** Official national language Hungarian **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** – **Preferred language of application** – **English accepted** No **Documents mandatory to be in official national language** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –

Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 4 **Time in weeks from submission to positive approval (maximum)** 9 **Time in weeks from submission to positive approval (average)** 6
Safety Reporting	**Investigator shall report SAE to** Institution Sponsor Trial Coordinator **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Set up contracts with external sponsor for trials including patients** Yes **Set up contracts with external sponsor for trials including healthy participants** No **Set up contracts with external sponsor for trials including vulnerable population** No
Investigator	**Entitled to be principal investigator** Physician **Entitled to be principal investigator for trials with patients** – **Entitled to be principal investigator for trials with healthy participants** – **Entitled to be principal investigator for trials with vulnerable population** –
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** No **Accepted format of Informed Consent (IC) form** Written consent

	Accepted format of IC form for studies including patients – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Elderly Unconscious Persons Incapacitated adults **Regulations concerning the inclusion or exclusion available** Yes **Applicable ethical regulations** Institutional
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Adults only Inconvenience, Pain, Discomfort Phase I trials **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** –
Funding	**Trials in patients financially supported by industry** Yes **Trials in healthy participants financially supported by industry** No **Trials in vulnerable population financially supported by industry** No **Funding is an issue during the approval process** No

Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor Not validated **Obligation to contract a liability insurance for trials including patients for** – **Obligation to contract a liability insurance for trials including healthy participants for** – **Obligation to contract a liability insurance for trials including vulnerable population for** – **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Audits Inspections Monitoring Standard Operating Procedures (SOP) Audit Trail Case Report Form (CRF) **Regularly performed methods in trials including patients** – **Regularly performed methods in trials including healthy participants** – **Regularly performed methods in trials including vulnerable population** – **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** – **Regularly performed audits in trials including patients** – **Regularly performed audits in trials including healthy participants** – **Regularly performed audits in trials including vulnerable population** – **Regularly performed audits - Additional information** internal and external audits are performed regularly in interventional trials

Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Yes

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki ICH-GCP Guidelines National regulatory requirements Institutional regulatory requirements **Applied regulatory conventions in studies including patients** – **Applied regulatory conventions in studies including healthy participants** – **Applied regulatory conventions in studies including vulnerable population** – **Applicable national laws** Hospital Act Data protection Act Drug act **Applicable national laws for patients** – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** Isotopes Tissue samples
Nutrition	**Nutrition considered as drug** Yes

Definition

Nutrition Study	**Definition available for Trials in patients** Yes **Definition available for Trials in healthy participants** No **Definition available for Trials in vulnerable population** Yes